(f) The *applicant* required to establish and maintain records and make reports required by this section includes any person whose name appears on the labeling of the drug as its manufacturer, packer, or distributor under an approval or who is engaged in the manufacturing, processing, packing, or labeling of the drug under an approval of the new animal drug application or any supplement to it; however, to avoid unnecessary duplication in the submission of reports, any such applicant's obligation to submit a report may be met by its submission on his behalf, designated as such, by another person responsible for reporting.

### § 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved application is in effect.

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) to which they relate, to the Center for Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

(2) Information concerning any bacteriological, or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this paragraph refers to conditions or developments not previously submitted as part of the new animal drug application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new animal drug application or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989]

### § 510.302 Reporting forms.

(a) The information described in § 510.300, except that described in paragraphs (b) (1) and (2) of that section, shall be submitted appropriately identified with the new animal drug application(s) to which they relate in duplicate on Form FD–2301 ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.''

(b) All adverse experiences with new animal drugs as described in § 510.300(b)(2) or § 510.301(b) whether or not related to a required periodic report submitted on a Form FD–2301, shall be reported on Form FD–1932 ''Adverse Drug Reaction'' (except as provided in paragraph (c) of this section). Reports of adverse drug experiences may be submitted initially in the form of a written communication, but any such communication shall be followed promptly (but not necessarily within the prescribed 15 working days) by a completed Form FD–1932. A separate ''Adverse Drug Reaction'' form should be submitted for each patient where feasible.

(c) In lieu of Form FD–1932 the holder of an approved new animal drug application may submit:

(1) A computerized report if the information contained therein and the sequence in which it is presented are equivalent to that required by Form

FD–1932 and the report is submitted in duplicate. Such reports will require initial approval by the Food and Drug Administration prior to use; and

(2) Copies of reports of reactions appearing in the published scientific literature may be submitted.

(d) Forms FD–1932 and FD–2301, with instructions for their use, may be obtained from the Food and Drug Administration, Department of Health and Human Services, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 41 FR 35844, Aug. 25, 1976; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

### § 510.305 Maintenance of copies of approved applications for animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location on the premises of each establishment to which an approved medicated feed application (Form FDA 1900) or supplemental application applies either:

(a) A copy of the approved medicated feed application (Form FDA 1900) and a sample of the approved labeling; or

(b) Identification of the approved medicated feed application in a single file or in a single readable document that includes:

(1) The application number and date of its approval;

(2) The name(s) of the premix(es) and the concentration of the drug(s) contained in the premix(es);

(3) The name(s) of the approved manufacturer(s) of the premix(es);

(4) The concentration of the drug(s) in the finished medicated feed; and

(5) A sample of the approved labeling.

[41 FR 36203, Aug. 27, 1976, as amended at 51 FR 7391, Mar. 3, 1986]

### § 510.310 Records and reports for new animal drugs approved before June 20, 1963.

(a) This section applies to new animal drugs, including antibiotics and medicated feed premixes bearing or containing new animal drugs, approved before June 20, 1963, on the basis of a new drug application, master file, antibiotic regulation, or food additive regulation.

(b) Sponsors of new animal drugs identified in paragraph (a) of this section shall submit the following information, in duplicate, for each dosage form of each such drug by November 21, 1980:

(1) If the new animal drug is currently marketed: (i) A copy of the label on the package of the drug and of the package insert or brochure bearing directions or information for use of the product.

(ii) If the label, brochure, or package insert is not identical in content to the one for the new animal drug as originally approved, the sponsor shall also report what changes have been made (other than minor changes in arrangement or printing or changes of an editorial nature) and explain why they were made, and shall submit data supporting such changes if the data have not previously been submitted.

(iii) If clinical experience reported to or otherwise received by the sponsor indicates the need for change in claims for effectiveness or in side effects, warnings, or contraindications in the labeling or advertising currently in use, the sponsor shall submit a supplemental application proposing such changes in the labeling and a showing that any advertising will be appropriately revised.

(iv) If the clinical or other experience reported to or otherwise obtained by the sponsor has revealed any information concerning any side effect, injury, toxicity, or sensitivity reaction, or any unexpected incidence or severity thereof, which by kind, or incidence or severity is not fully disclosed in the labeling, whether or not determined to be attributable to the drug, this information shall be submitted. Such information shall include full reports of all available information with respect to any deaths apparently related to a drug administration whether or not determined to be attributable to the drug. Any such information previously submitted need not be resubmitted.

(v) If the clinical or other experience reported to or otherwise obtained by the sponsor within the past 2 years has revealed any information with respect to a distributed batch concerning any mixup in the drug or its labeling with another article; any bacteriological or